

**d.) Remarks**

Claims 1, 3, 5, and 22-24 have been canceled, claims 6, 7, 11 and 12 have been amended, and claims 25-30 have been added. Accordingly, claims 6-19 and 25-30 are currently pending.

Applicant respectfully notes that the examiner alleges in the Office Action that all claims except claim 11 stand withdrawn. However, claims 6-19 were elected for continued prosecution and the limitation to claim 11 was a species restriction. Accordingly, all claims not withdrawn are currently pending. Nevertheless, as claim 11 is believed to be allowable, and all elected claims are generic thereto, applicant respectfully requests that claims 6-19 and new claims 25-30 be examined and considered allowable as well.

Claims 6, 7, 11, and 12 have been amended to incorporate claim 1 and be considered independent claims, and new claims 25-30 added to repeat claims 18 and 19 for each independent claim. Support for these amendments and new claims can be found throughout the specification (*see* specification page 5, line 25, “1000 cfu/ml”; and page 12, line 11, “10,000 cfu/ml”), and also in the original claims (*see* claims 18 and 19). No new matter or new issues are believed presented.

**Remarks Regarding IDS**

The Examiner notes that an English language version of JP 52078 95 was not provided. No English version of this document is currently available to the undersigned; however, the undersigned was able to obtain an English-language abstract. A copy of that abstract is enclosed and applicant respectfully requests that the abstract be considered by the examiner. A revised Form PTO-1449 with the JP patent indicated as an “abstract” is enclosed (or the examiner can indicate such on the previously filed Form PTO-1449. As the article was previously submitted, a new Form PTO-1449 is not believed to be required. However, a Supplemental IDS can be submitted if necessary.

**Remarks Regarding Drawings**

The Examiner alleges that this application was filed with informal drawings, which are acceptable for examination purposes, but notes that formal drawings will be required. Copies of the formal drawings submitted with the parent application are enclosed.

**Remarks Regarding Alleged Double-Patenting**

Claim 11 allegedly stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-25 of co-pending Application No. 10/053,871. Applicant respectfully traverses this rejection. An appropriate Terminal Disclaimer is attached hereto and this rejection is moot.

**Remarks Regarding 35 U.S.C. § 112, First Paragraph**

Claim 11 stands rejected, under 35 U.S.C. § 112, first paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

It is alleged that the phrases “viability marker” and “reporter molecule” are indefinite. Applicant respectfully disagrees. Both phrases are fully and clearly defined in the specification and used in the context of art understood meanings.

As recited in the specification, a viability marker is a substrate of the microorganism which is “... metabolized by the microorganism to a single water-insoluble marker molecule” (specification, page 7, lines 13-15). As also recited in the specification, a reporter molecule can be, for example, an enzyme a luminescent protein, or a radioisotope (*see* specification at page 10, lines 5-6). The phrase reporter molecule is further defined by the examples disclosed of claim 14. Thus, the specification clearly satisfies § 112.

In addition, applicant respectfully contends that both phrases are well known to those of ordinary skill in the art, which would also satisfy § 112. For example, a simple search for these phrases in the patent literature identified eight issued patents, most filed and/or issued prior to the

filing of the instant application. The undersigned also located an abstract dated January 27, 1997, which also uses the phrase “viability marker.” Copies of the abstracts of these patents (Patent Nos. 4,378,428; 4,785,080; 5,106,950; 5,235,039; 5,356,774; 5,362,628; 5,858,697; 6,743,578) well as the publication abstract are all enclosed.

In sum, both phrases are well-know in the field and also clearly disclosed in the specification, with both discussion and examples. Any one of these factors alone would satisfy § 112 and, thus, no more can be required.

Accordingly, the rejection of claim 11, under 35 U.S.C. § 112, first paragraph, is overcome and applicant respectfully requests that it be withdraw.

#### **Remarks Regarding 35 U.S.C. § 103(a)**

Claim 11 stands rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Shih et al. (U.S. Patent No. 4,026,767) in view of Harlow and Lane. Applicant respectfully traverses this rejection.

In an effort to expedite prosecution, applicant has amended the independent claims (6, 7, 11 and 12) to recite that the claimed method is capable of detecting less than 10,000 cfu of microorganisms/ml. The claimed sensitivity of applicant’s methods is not suggested by Shih in view of Harlow and Lane, or any of the cited references either alone or in combination.

Thus, the rejection of claim 11, under 35 U.S.C. § 103(a), is moot and applicant respectfully requests that it be withdraw.

#### **Conclusion**

The elected species is now believed to be allowable. Applicant respectfully requests that all other alleged species be promptly examined. All species are believed to be allowable and, accordingly, the application is in condition for allowance. The prompt issuance of a Notice of Allowance is respectfully requested.

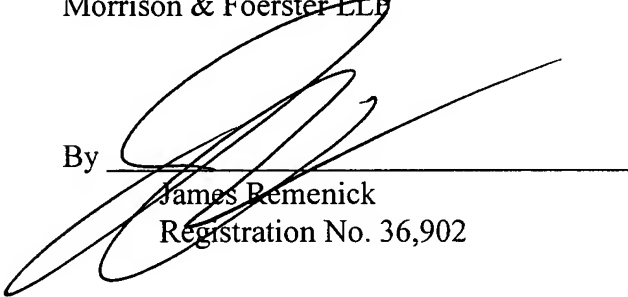
If the examiner has any further questions regarding this case, the undersigned would welcome an interview. Please feel free to contact the undersigned at the telephone number indicated.

If there are any additional fees due with the filing of this Amendment, including any additional fees for a further extension of time, not herein accounted for, applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 03-1952.

Respectfully submitted,  
Morrison & Foerster LLP

Date: November 19, 2004

By



James Remenick  
Registration No. 36,902

Enclosed: Terminal Disclaimer  
Formal Drawings  
Abstract of JP 52078 95  
Nine published abstracts

**Customer No. 25227**  
Morrison & Foerster LLP  
1650 Tyson's Blvd., Suite 300  
McLean, VA 22102  
Tel: (703) 760-7700  
Fax: (703) 760-7777